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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
[30Day-19-1170]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Canine Leptospirosis Surveillance in Puerto Rico to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on January 29, 2019 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of

the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Canine Leptospirosis Surveillance in Puerto Rico (OMB Control No. 0920-1170, Exp. Date 03/31/2019) -- Reinstatement with Change -- National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of High-Consequence Pathogens and Pathology (DHCPP), Bacterial Special Pathogens Branch (BSPB), requests three years of OMB approval for a reinstatement to the approved ICR "Canine Leptospirosis Surveillance in Puerto Rico." Approved methods of information collection will not change.

Active surveillance allows for the collection of prospective data on acute cases to determine the incidence and distribution of leptospirosis in dogs, assess risk factors for infection, characterize circulating *Leptospira* serovars and species, assess applicability of vaccines currently in use based on serovar determination, and assess rodent, livestock, and wildlife reservoirs of leptospirosis based on infecting serovars found in dogs. Findings from this study will aid in the development of evidence-based, targeted interventions for the

prevention of canine leptospirosis, be used to focus human leptospirosis surveillance efforts, and guide future investigations on leptospirosis in humans and animals in Puerto Rico.

The information collection for which approval is sought is in accordance with BSPB's mission to prevent illness, disability, or death caused by bacterial zoonotic diseases through surveillance, epidemic investigations, epidemiologic and laboratory research, training and public education. Authorizing Legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241). Successful execution of BSPB's public health mission requires data collection activities in collaboration with the state health department in Puerto Rico and with local veterinary clinics and animal shelters participating in the study.

These activities include collecting information about dogs that meet the study case definition for a suspect case of leptospirosis seen at participating veterinary clinics and shelters. Participating veterinarians and their veterinary staff collect information by interviewing the dog owner (shelters are an exception as dog will not have an owner) and reviewing medical and administrative records, as necessary. Basic information about the participating sites will also be collected for study management and to enhance data analysis.

Information will be collected using paper forms and provided in Spanish. Staff at participating sites find it easier to complete a paper copy when abstracting medical record information and interviewing owners for information about their dog's risk factors and symptoms. Study coordinators will enter collected data into an electronic database.

The types of information being collected include information about the dog's signalment, location of residence, environmental risk factors, vaccination history, clinical signs and symptoms, laboratory results, and clinical outcome. Approval of this reinstatement ICR will allow BSPB to continue to collect these information which can help inform animal public health and will help contribute to a One Health understanding of leptospirosis in Puerto Rico.

BSPB estimates involvement of at least 411 respondents (385 from the general public and 26 veterinarians and their veterinary staff) and estimates a total of 168 hours of burden for research activities each year. The collected information will not impose a cost burden on the respondents beyond that associated with their time to provide the required data.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per	Average Burden per
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			Respondent	Response (in hours)
Veterinarian	Enrollment Questionnaire	26	1	5/60
	Log Sheet	26	24	1/60
	Case Questionnaire	26	24	10/60
General public	Case Questionnaire	624	1	5/60

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